DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0329]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on How to Use E-Mail to Submit Information to the Center for Veterinary Medicine, 21 CFR 11.2—(OMB Control N0. 0910–0454)—Extension

The Center for Veterinary Medicine (CVM) is responsible for developing and administering guidances that explain how to adhere to the electronic records; electronic signatures regulations (part 11 (21 CFR part 11)). These regulations allow sponsors to submit part or all of records to FDA electronically in lieu of paper, unless the paper records are specifically required by regulation, if the requirements of part 11 are met, and the documents to be submitted electronically are identified in Public Docket No. 92S–0251. These regulations comply with the Government Paperwork Elimination Act (GPEA) (Public Law 105–277). The GPEA requires Federal agencies, by October 21, 2003, to give persons who are required to maintain, submit, or disclose information the option of doing so electronically when practicable as a substitute for paper.

This guidance document describes the procedures persons who submit information to CVM should follow, if they want to file submissions electronically. This guidance instructs those who wish to submit information to CVM by e-mail to first register with the center. Registration entails sending a letter, on paper or electronically, to CVM with a sponsor password and the names, phone numbers, mail and e-mail addresses of a sponsor coordinator and each person who will submit information electronically to CVM. Other information collection provisions relate to electronic submissions by individuals and electronic submissions to make changes to the sponsor's

registration. CVM will use all the information submitted to process electronic submissions. The likely respondents to this collection of information are new animal drug sponsors.

In the **Federal Register** of August 7, 2003 (68 FR 47077), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

We estimate the burden for this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3,538	70	2	140	.5	70

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimate of the times required for record preparation is based on agency communication with industry. Other information needed to calculate the total burden hours are derived from agency records and experience.

Dated: January 16, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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